OREGONIANS FOR FOOD & SHELTER
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PARC Board Consultants

RE: Protocols for Triangle Lake Exposure Investigation

On July 15, 2011 you (or a representative from your agency) met with forestland stakeholders in Salem at the AOI building to discuss plans for the Triangle Lake Exposure Investigation scheduled for the August/September 2011 timeframe. At that meeting, Captain Kauffman stated that the biomonitoring would be done using the CDC's (Center for Disease Control) Institutional Review Board (IRB) to approve the sampling design, collection and analytical protocols to be used for the urine testing in this investigation.

Although it is important to have all aspects of the investigation thoroughly reviewed from a scientific rigor perspective, perhaps the two most important are the procedures and protocols used for: (1) selecting the participant population, and (2) the integrity and security of sample collection and handling.

Integrity and Security of Sample collection and Handling: To date, stakeholder representatives that were at the July 15 meeting have not received communications confirming that a CDC protocol review has been done. We also have not seen written documentation on the actual procedures/protocols that will be used. To the contrary, we have now heard of at least three vastly different collection concepts: (1) drop off and pick up a "kit" on each participant's home doorstep; (2) collect specimen samples at a central, public location; and the latest, (3) visit a participant's household and have the sample drawn in the home.

Federal agencies and private laboratories alike have very detailed protocols for urine biomonitoring and agree that security during specimen collection and handling are essential quality assurance and quality control (QA/QC) considerations.

"DOT Urine Specimen Collection Guidelines for the U.S Department of Transportation" (49CFR Part 40), was revised in December 2006. The 42-page guideline states, "The procedures for collection of urine under these rules are very specific and must be followed whenever a DOT-required urine specimen collection is performed." It goes on to note, "Without the collector assuring the integrity of the specimen and collection process, the test itself may lose validity."

SECTION 2. COLLECTION SITE (pp. 5-6) gives very explicit security requirements and procedures to protect against adulteration and provides for secure handling and storage of specimens. SECTION 6. COLLECTION PROCEDURES (pp.10-18) begins with the following warning: "The collector must do the following before each collection to deter potential tampering, adulteration, alteration, or substitution of the specimens…" Reading these guidelines, it is obvious that U.S. DOT believes rigorous protocols and procedures for collection and testing of urine samples are essential to valid and legally defensible results.

ExperTox, a Texas-based, private laboratory specializing in urine analyses, condensed their "Urine Collection Protocol" to one page of very specific steps to insure the integrity of the sample. Albeit brief, it likewise starts with rigorous procedures prior to taking a sample -- securing the collection area and searching for hidden adulterants or substitute urine specimens on the site or on the donor. It also includes applying a temperature strip to the outside of the sample bottle to measure temperature within four minutes of collection to protect against substitution of an alternate specimen.

Selection of Biomonitoring Participants: There appears to be changing and often conflicting information regarding the size and location of the area selected for the investigation -- as well as the details of how the participants for bio-monitoring are being selected. Variations being rumored include differing radii around recently harvested timber units and/or selection of townships around Triangle Lake or Highway 36. Participants from within the designated geographic boundaries would be comprised of residents who voluntarily signed-up or who attended the community meeting on the evening of July 14 – a highly biased group. First we heard that only one participant from a residence would be eligible, but later heard that due to lack of volunteers, multiple persons from one address could volunteer and participate.

Experts in biomonitoring caution using a self-selection process or volunteer approach. The National Research Council Committee on Human Biomonitoring for Environmental Toxicants published a comprehensive reference book in 2006 on "Human Biomonitoring for Environmental Chemicals" which discusses the various aspects of conducting valid biomonitoring. In the discussion on selection of the participants for the study, it strongly advises against using a volunteer or self-selected population. It states:

"(T)here have been numerous reports of groups assembled because they responded to solicitations to participate in studies of environmental effects. Although it may be possible to draw some insights from such groups of self-selected volunteers, they cannot be presumed to be representative of a population of interest, nor can any valid comparisons with unsampled members of the population be made.

"Selection bias is the Achilles heel of such samples. Therefore when researchers use convenience samples for assessing population characteristics such as prevalence, incidence, or causal relationships, they must justify the validity of the sample. At a minimum, when such convenience samples are reported, the strategy used for recruitment and selection must be made completely transparent and explicit so that scientists can assess the distortions or biases that may result from analyzing measurements in such groups as though they were true population samples.

"The committee recommends that if convenience samples are chosen, then funders, reviewers, and editors of peer-reviewed journals must insist on complete characterization of how

each sample was chosen so that misinterpretation—intentional or not—is less likely. Even if those principles are rigorously adhered to, there remains in every situation an important degree of uncertainty because of random variation—who was sampled and who was not—so all results will ultimately need be expressed with respect to that uncertainty."

It is also presumed that whatever method of seeking potential volunteers or participants is used, that efforts will be made to randomize those actually submitting samples. Focusing on members of the Pitchfork Rebellion, Forestland Dwellers, Oregon Toxics Alliance or other such avowed anti-pesticide groups will obviously heighten the concern over and need for specimen security during the collection and chain of custody processes.

In closing, OFS does support a properly conducted, scientifically robust investigation into alleged herbicide exposures in the area. In order to have confidence that the process will indeed follow generally accepted scientific standards, however, I am asking that you provide in writing the protocols and procedures to be used for both participant selection and the security of sample collection/handling **BEFORE** the investigation is launched.

It is my understanding that sample collection and interviews are still scheduled to start on Monday, August 29. Unfortunately, this does not leave much time for suggestions or recommended changes to improve the integrity of process to be used.

Sincerely,

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